

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 46 is requested to be cancelled.

Claims 37 and 53 are currently being amended. Support for the claim amendments can be found, at least, in the specification, e.g., page 6, lines 1-4, page 7, lines 9-16, the figures, e.g., figures 1-3, and the claims as filed, e.g., claim 46. No new matter has been added.

Claims 62-63 are being added. Support for the new claims can be found, at least, in the specification, e.g., page 6, lines 1-4, page 7, lines 9-16, the figures, e.g., figures 1-3, and the claims as filed, e.g., claim 46. No new matter has been added.

This amendment adds, changes and deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 37-45 and 47-63 are now pending in this application.

**Rejections under 35 U.S.C. 103**

The Office Action rejected claims 37-41, 44-48, 51-54 and 56-61 under 35 U.S.C. 103(a) as being unpatentable over Hei et al. (US 6,544,727) (hereinafter Hei) in view of Kobashi (US 5,428,993) in view of DeVries (US 4,379,452) and in view of Siegal (US 4,450,375). The Office Action rejected claims 42-43 under 35 U.S.C. 103(a) as being unpatentable over Hei, in view of Kobashi in view of DeVries, and in view of Siegal as applied to claims 37-41, 44-48, 51-54 and 56-61 above, and further in view of Matkovich (US 5,126,054). The Office Action rejected claims 37, 49 and 50 under 35 U.S.C. 103(a) as being unpatentable over Hei, in view of Kobashi

et al., in view of DeVries, and in view of Siegal as applied to claims 37-41, 44-48, 51-54, and 56-61 above, and further in view of Burney et al. (US 3,478,673) (hereinafter Burney) and in view of Wrasidlo et al. (US 4,937,196) (hereinafter Wrasidlo). Applicant respectfully disagrees with these rejections.

The Office Action fails to provide an explanation with articulated reasons, findings of fact and the rationale to support the rejection. For Hei, Kobashi, DeVries, and Siegal, the Office Action merely states a conclusion that it “would have been obvious, to one of ordinary skill in the art, at the time the invention was made, to modify” the references. (Office Action dated 1/23/2009, page 8). In particular, the Office Action merely provides two clauses for combining four references: “it can prevent the wasting of reagents” and “an advantage of the the fluid distribution modules is that it is simply, economical to manufacture and highly effective for the intended purpose of rapidly and accurately controlling fluid flow.” (Office Action dated 1/23/2009, page 8). These two clauses do not provide articulated reasons for the rejection, as described in MPEP 2141, such that the applicant is aware of the reasons for the rejection of the claims.

Further, for the other 103 rejections, the Office Action merely provides short clauses without an articulated reasons for the combinations. For Hei, Kobashi, DeVries, Siegal, and Matkovich, the Office Action merely provides one clause for combining the five references: “where the motivation would have been to remove harmful components.” (Office Action dated 1/23/2009, page 10). For Hei, Kobashi, DeVries, Siegal, Burney, and Wrasidlo, the Office Action merely provides one clause for combining the six references: “because all the claimed elements were known in the prior art, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention.” (Office Action dated 1/23/2009, page 11). For Hei, Kobashi, DeVries, Siegal, and Hudak, the Office Action merely provides one clause for combining the five references: “where the motivation would have been to provide hospitals with

rare cell genotype blood.” (Office Action dated 1/23/2009, page 12). As such, none of these clauses provide articulated reasons for the rejections, as described in MPEP 2141, such that the applicant is aware of the reasons for the rejection of the claims.

MPEP 2141 describes that “[w]hen making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.” MPEP 2141. Further, “[o]nce the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103. 35 U.S.C. 132 requires that the applicant be notified of the reasons for the rejection of the claim so that he or she can decide how best to proceed. Clearly setting forth findings of fact and the rationale(s) to support a rejection in an Office action leads to the prompt resolution of issues pertinent to patentability.” MPEP 2141. In addition, the Office Action fails to provide any reasoning beyond just an “obvious to try” reason, which is not sufficient for a showing of obviousness. (“a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try'” MPEP 2141).

Independent claim 37, as now amended, is directed to a biological cell processing system. The biological cell processing system includes “a processing module having a processing chamber, the processing chamber defining a processing chamber volume” and “a control module, wherein the control module changes the processing chamber volume based on a volume of fluid in the processing chamber,” as recited in claim 37, as now amended. Independent claim 53, as now amended, includes similar claim limitations.

Hei describes methods and devices for the removal of psoralens and psoralen photoproducts from blood products. (Hei: Abstract). In particular, Hei describes an exemplary apheresis system having fluid pumps, a centrifuge, fluid lines, and a computerized controller.

(Hei: Col. 66, ll. 40-65; see also FIG. 49). With respect to a processing chamber, the Office Action relies on the disclosure of Hei in Figures 20 and 37; col. 97, lines 40-65. These figures illustrate fluid bags, as may be used in blood processing. The bags are described as being interconnected with flexible tubing 200 to create a blood transfer set. (Hei: Col. 97, ll. 16-19). Hei does not describe “a processing module having a processing chamber, the processing chamber defining a processing chamber volume” and “a control module, wherein the control module changes the processing chamber volume based on a volume of fluid in the processing chamber,” as recited in claim 37, as now amended. In contrast, Hei describes fluid bags for transfer of blood products by expressing the bag utilizing, e.g., a Fenwalim device for plasma expression, and not a control module for changing the processing chamber volume based on a volume of fluid in the processing chamber.

Kobashi describes an automatic analyzer having a function for detecting a remaining quantity of liquids being used. (Kobashi: Abstract). As described at column 4, lines 50-58, in relation to FIG. 2, a reagent container 12 is connected to the analyzer 10 through a tube 14. (Kobashi: Col. 4, ll. 50-58). The container 12 is put on a weigh sensor 16, and a weight of the container 12 is transmitted to the analyzer for processing. (Kobashi: Col. 4, ll. 50-58). Kobashi does not cure the deficiencies of the other cited references with respect to describing “a processing module having a processing chamber, the processing chamber defining a processing chamber volume” and “a control module, wherein the control module changes the processing chamber volume based on a volume of fluid in the processing chamber,” as recited in claim 37, as now amended. In contrast, Kobashi describes a weight sensor for liquids to be used in automatic analyzers that transfers the weight to an analyzer for processing and not a control module for changing the processing chamber volume based on a volume of fluid in the processing chamber.

DeVries describes a compact and disposable monitor and fluid circuit assembly for collecting a desired blood component. (DeVries: Col. 1, ll. 19-23). The monitor and fluid circuit assembly 11 is described as including a fluid circuit 16 including plurality of flexible plastic

tubings that form fluid couplings between various parts of the fluid circuit 16. (DeVries: Col. 3, ll. 1-8). The tubings are described as being received through a housing 18 that, having monitor devices mounted therein. (DeVries: Id., ll. 9-10). The tubing is describes as being series coupled to a high pressure monitoring device 64. (DeVries: Id., ll. 56-59). In reference to FIG. 5, the monitoring device 64 includes an air filled closed chamber 184 having a flexible diaphragm 135 forming part of one wall of the flow through chamber and an outer wall 136 situation adjacent to an associated pressure transducer. (DeVries: Col. 7, ll. 51-55). The outer wall 136 in DeVries is situated adjacent to a sensor 63, 65 or 85 “which are pressure transducers and which sense changes in pressure on the outer wall 136.” (DeVries: Col. 7, lines 50-56). DeVries does not cure the deficiencies of the other cited references with respect to describing “a processing module having a processing chamber, the processing chamber defining a processing chamber volume” and “a control module, wherein the control module changes the processing chamber volume based on a volume of fluid in the processing chamber,” as recited in claim 37, as now amended. In contrast, DeVries describes a compact and disposable monitor and fluid circuit assembly that senses changes in pressure via a flexible diaphragm and not a control module for changing the processing chamber volume based on a volume of fluid in the processing chamber.

Siegal describes a “piezoceramic bender [that] cooperates with an impacting member, membrane and valve seat to provide a novel piezoelectric transducer arrangement for achieving desired rapid and accurate control of fluids under pressure in a variety of different applications.” (Siegel: Abstract). Siegal does not cure the deficiencies of the other cited references with respect to describing “a processing module having a processing chamber, the processing chamber defining a processing chamber volume” and “a control module, wherein the control module changes the processing chamber volume based on a volume of fluid in the processing chamber,” as recited in claim 37, as now amended. In contrast, Siegal describes a fluid control device for use in selectively dispensing desire quantities of fluid using a piezoelectric device and not a control module for changing the processing chamber volume based on a volume of fluid in the processing chamber.

Matkovich describes standard fluid bags and tubing as may be used in blood processing and in particular, a gas vent means for venting gases in a liquid transfer or delivery system. (Matkovich: Col. 1, ll. 35-37). The vent means in Matkovich “includes a housing, a first microporous membrane that is wettable by the liquid to be transferred or delivered by the system and a second microporous membrane, capable of passing gas therethrough but which is not wettable by the liquid to be transferred.” (Matkovich: Col. 1, ll. 38-42). Matkovich does not cure the deficiencies of the other cited references with respect to describing “a processing module having a processing chamber, the processing chamber defining a processing chamber volume” and “a control module, wherein the control module changes the processing chamber volume based on a volume of fluid in the processing chamber,” as recited in claim 37, as now amended. In contrast, Matkovich describes a gas vent means and not a control module for changing the processing chamber volume based on a volume of fluid in the processing chamber.

Burney describes “an air operated coffee brewer having a movable stopper and brew cylinder together with an air cylinder with piston and rod connected to the stopper to move the stopped into sealing relation with the brew cylinder during the brew cycle.” (Burney: Col. 1, ll. 13-17). Burney does not cure the deficiencies of the other cited references with respect to describing “a processing module having a processing chamber, the processing chamber defining a processing chamber volume” and “a control module, wherein the control module changes the processing chamber volume based on a volume of fluid in the processing chamber,” as recited in claim 37, as now amended. In contrast, Burney describes an air operated coffee brewer and not a control module for changing the processing chamber volume based on a volume of fluid in the processing chamber.

Wrasidlo describes a bioreactor in which cells are confined to “a compartment formed by porous hydrophilic sheet membranes through which a nutrient solution diffuses in and exocellular products and metabolic waste diffuse out.” (Wrasidlo: Abstract). Wrasidlo does not cure the deficiencies of the other cited references with respect to describing “a processing module having a processing chamber, the processing chamber defining a processing chamber volume”

and “a control module, wherein the control module changes the processing chamber volume based on a volume of fluid in the processing chamber,” as recited in claim 37, as now amended. In contrast, Wrasidlo describes a bioreactor that is an artificial environment for the growth of organisms and not a control module for changing the processing chamber volume based on a volume of fluid in the processing chamber.

Accordingly, none of the cited references, combined or separately, teach, suggest, or describe the claim limitations of independent claims 37 and 53, at least, for the reasons described above. As such, the rejection of claims 37 and 53 should be withdrawn, and these claims, as now amended, are now in a condition for allowance. Dependent claims 38-45, 47-52, and 53-61 depend, directly or indirectly, from independent claims 37 and 53, respectively. As such, the rejection of claims 38-45, 47-52, and 53-61 should be withdrawn, and these claims, as now amended, are now in a condition for allowance based, at least, on the reasons set forth above with respect to independent claims 37 and 53 and based their individual claim limitations.

### **New Claims 62-63**

Claim 62 is directed to a processing chamber that “includes a movable wall to adjust the processing chamber volume.” Claim 63 includes similar limitations. Claims 62 and 63 depend directly from independent claims 37 and 53, respectively.

None of the cited references, separately or combined, teach, suggest, or describe a processing chamber that “includes a movable wall to adjust the processing chamber volume.” As discussed above, none of the cited references teach, suggest, or describe the claim limitations of independent claims 37 and 53. Accordingly, claims 62 and 63 are in a condition for allowance, at least, based on their dependency from independent claims 37 and 53, respectively, and based on their individual claim limitations.

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Applicant believes that the present application is now in condition for allowance.  
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a  
telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be  
required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to  
Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit  
card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or  
incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to  
Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of  
papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136  
and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 1/22/2010

FOLEY & LARDNER LLP  
Customer Number: 48329  
Telephone: (617) 342-4093  
Facsimile: (617) 342-4001

By 

Joseph M. Maraia  
Attorney for Applicant  
Registration No. 55,926